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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
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3762

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/728,072

Applicant(s)

HEIL ET AL.

Examiner

Michael Kahelin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 33-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32, 48-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-32 and 48-66, drawn to a cardiac lead apparatus with drug phoresis, classified in class 607, subclass 120.
 - II. Claims 33-47, drawn to a method for delivering a lead, classified in class 607, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). The apparatus as claimed can be used to practice another and materially different process, not requiring delivering the lead into subcutaneous non-intrathoracic tissue of the patient, but the heart of a patient. It is noted that the functional use recitation in the apparatus is not a method step.
3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Mark Hollingsworth on 1/5/2007 a provisional election was made without traverse to prosecute the invention of group I, claims 1-32 and 48-66. Affirmation of this election must be made by applicant in replying to this Office action. Claims 33-47 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 4, 5-7, 9, 17-19, 21, 24, 32, 48, 49, 54-56, and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellinwood, Jr. (US 4,146,029, hereinafter "Ellinwood").

7. In regards to claims 1, 18, 21, 48, and 55, Ellinwood discloses an implantable system having a lead (248 and 251); a cardiac electrode supported by the lead body (250) capable of subcutaneous, non-intrathoracic placement and for cardiac monitoring (col. 14, line 35); and a driving arrangement for phoresis delivery of a pharmacological agent from the lead/can to subcutaneous tissue (212, 248, 250 and 251) optionally via a detachably coupled unit (col. 31, line 56). Please note that Ellinwood's electrode is capable of non-intrathoracic placement because it is implantable and of a size to fit

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under the skin. Also, the pharmacological agent is delivered from the can to the tissue via the lead/catheter assembly, meeting the limitations of claim 18.

8. In regards to claim 2, the driving arrangement comprises the electrode (250).

9. In regards to claim 4, the electrode is an electrode array (Fig. 13, two electrodes).

10. In regards to claims 5, 19, 49 and 56, the driving arrangement comprises a conductor to provide electrophoresis (col. 32, line 1).

11. In regards to claim 6, the pharmacological agent provides therapeutic treatment localized to an area surrounding a portion of the dissection path (because the agent is not delivered vascularly) via 247.

12. In regards to claim 7, the agent is provided at a plurality of locations (Fig. 8).

13. In regards to claim 9, the agent is delivered at a collar (247).

14. In regards to claims 17, 32, 54 and 66, the agent promotes hemostasis (col. 30, line 39).

15. In regards to claim 25, the can comprises a reservoir and port (Fig. 12).

16. Additionally, claims 1, 2, 4, 5, 9, 16-19, 21, 22, 31, 32, 48, 49, 53-56, 58, 65, and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Kieval (US 6,178,349, hereinafter "Kieval").

17. Referring to claims 1-2, 21, 48, and 55, Kieval teaches an implantable medical device for treatment of cardiovascular disorders that includes an implantable pulse generator, an electrode and a reservoir (see column 3, lines 57-61). The electrode is

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connected to the pulse generator by a lead, and a reservoir to delivery an alkaloid to the tissue is coupled to the lead (see figures 1 and 2, elements 90, 96, 98, 92, 94, 116, 114, 120, 122, 124, and column 4, lines 49-67, and column 5, lines 28-58). Kieval further teaches that the electrode stimulates a nerve that affects cardiovascular activity (see column 3, lines 11-16; which is being interpreted as cardiac electrical stimulation because it is electrical stimulation corresponding to cardiac function).

18. Regarding claim 4, Kieval teaches that the electrode may include a plurality of individual electrodes (see column 5, lines 42-43) and that a steroid-eluting body may be associated with the electrode (see column 5, lines 43-45) and that the base and the container may be integrally formed (see column 6, lines 27-28).

19. With reference to claims 5, 19, 22, 49, 56, 58, Kieval discloses delivery of a nerve stimulating drug regulated by an apparatus that is an electromagnetic-based device and includes magnets electrically connected to the pulse generator by a lead (see column 7, lines 3-24 and lines 49-53).

20. Regarding claim 9, Kieval teaches that the base of the electrode assumes a cuff configuration and the reservoir is associated with the configuration (see figure 2 and column 5, lines 48-50).

21. With reference to claims 16, 31, 53, and 65, Kieval discloses that the reservoir elutes veratrum alkaloid (see column 6, lines 3-5).

22. Referring to claims 17, 32, 54, and 66, the nerve stimulation drug simulates a pressure rise in the carotid sinus bodies (see column 6, lines 46-48).

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23. With regards to claim 18, Kieval discloses the system described above, and further teaches that the can is configured to provide phoresis delivery because the pulse generator can control the regulating apparatus (see column 7, lines 3-24).

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

25. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

26. Claims 3, 8, 10-16, 20, 23, 25-27, 29-31, 50-53, 57, and 63-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellinwood. Ellinwood discloses the essential features of the claimed invention except for a sonophoresis driving mechanism; a pharmacological agent impregnated in a membrane coating; a pharmacological agent infused in a porous doped polymeric structure; or an

analgesic/anesthetic, antibiotic/antiseptic, or steroid/anti-inflammatory agent. It is well known in the art to provide implantable devices with sonophoresis driving mechanisms to provide deeper penetration of non-ionically charged medications; pharmacological agents impregnated in membrane coatings to provide an easily manufactured device with medication delivered over a large surface area of the device; pharmacological agents infused in porous doped polymeric structures to provide slow and controlled release of a drug over a long period of time; and analgesic/anesthetic, antibiotic/antiseptic, and steroid/anti-inflammatory agents to provide a less painful recovery from implantation, a lower likelihood of infection, and decreased cell proliferation. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Ellinwood's invention with a sonophoresis driving mechanism to provide deeper penetration of non-ionically charged medications; a pharmacological agent impregnated in a membrane coating to provide an easily manufactured device with medication delivered over a large surface area of the device; a pharmacological agent infused in a porous doped polymeric structures to provide slow and controlled release of a drug over a long period of time; and an analgesic/anesthetic, antibiotic/antiseptic, or steroid/anti-inflammatory agent to provide a less painful recovery from implantation, a lower likelihood of infection, and decreased cell proliferation.

27. Claims 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellinwood. Ellinwood discloses the claimed invention, including various configurations of the medication/pacing control housing(s) but does not disclose expressly the driver

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provides a phoresis power signal to the implanted device, wherein the control signal is DC, AC, or AC with a DC offset. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the driver as taught by Ellinwood with the various control signals because applicant has not disclosed that AC, DC or AC with DC offset provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the control signal as taught by Ellinwood because both systems signal to the drug delivery module when medication is needed. Therefore, it would have been an obvious matter of design choice to modify the control signals as disclosed Ellinwood to obtain the invention as specified in the claims.

28. Claims 22 and 58 rejected under 35 U.S.C. 103(a) as being unpatentable over Ellinwood in view of Kroll et al. (US 6,282,444, hereinafter "Kroll"). Ellinwood discloses the essential features of the claimed invention except for a lead and can that are configured to provide phoresis by providing a potential between the lead and the can. Kroll teaches of providing a can/electrode configuration that provides phoresis by providing a potential between the lead and the can to drive a drug to a desired area of effect. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Ellinwood's invention with a can/electrode configuration that provides phoresis by providing a potential between the lead and the can to drive a drug to a desired area of effect.

29. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ellinwood as applied to claim 27 above, and further in view of Munshi (US 6,295,474,

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hereinafter "Munshi"). Ellinwood discloses the essential features of the claimed invention except for a can coating that covers at least 25% of the surface of the can. Munshi teaches of providing a can coating that covers at least 25% (Fig. 2B and col. 6, line 22; the can is coated with the drug-containing polymer, thus covering at least 25% of the can) to maximize the surface area, thus device/tissue drug and electrical interaction. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ellinwood's invention by providing a can coating that covers at least 25% of the can to maximize the surface area, thus device/tissue drug and electrical interaction.

30. Additionally, claims 3, 6-8, 10-15, 25-26, 29-30, 50-52, 57, and 63-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kieval in view of Shapland et al (U.S. 5628730). Kieval discloses the system and method described above, but does not disclose a transducer that provides sonophoresis; providing therapeutic treatment localized to a dissection path; that the pharmacological agent is provided at a plurality of locations on the lead body; that the pharmacological agent is impregnated into a membrane provided on the lead; that the lead comprises a polymeric structure, a porous region, or a doped polymer matrix; that the pharmacological agent is disposed on a coating on the lead; that the pharmacological agent is an analgesic or anesthetic; that the pharmacological agent is an antibiotic; that impelling the pharmacological agent comprises generating ultrasonic waves for impelling the pharmacological agent ultrasonically, impelling a plurality of pharmacological agents, impelling a first

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pharmacological agent using electrophoresis and impelling a second pharmacological agent using sonophoresis; or delivering a can into subcutaneous non-intrathoracic tissue of the patient, the can comprising an electrode or electrically conductive region, and a pharmacological agent and impelling using phoresis the pharmacological agent from at least a portion of the can to the subcutaneous non-intrathoracic tissue.

Shapland et al. disclose an apparatus and method for delivering a drug or combination of drugs selectively and locally to an internal body tissue (see column 2, lines 22-25).

The catheter includes a drug transport wall for engagement with a local area of the passageway wall or tissue and a drug chamber for receiving a selected drug. The wall is constructed of at least perforated, permeable, or semi-permeable material through which the drug is to selectively pass (see column 2, lines 34-47 and 53-57). The catheter may be coated on its outer surface with hydrogel to improve contact with the vessel wall. The hydrogel may contain the drug to be delivered. The hydrogel may also be coated on the inside wall of a catheter for similar drug delivery (see column 8, lines 23-33). The drugs that are delivered by the device include antibiotics and sensitizers (see column 12, lines 53-58). Shapland et al. also disclose using phonophoresis, and that to perform phonophoresis, the catheter uses a piezoelectric transducer (see column 13, lines 3-52). Phonophoresis achieves greater penetration and more readily delivers an entire molecule (see column 13, lines 10-14). Transducers transfer one form of energy to another form of energy. Further, it would be obvious to combine the system and method taught by Kieval with the elements disclosed by Shapland et al. because providing drug delivery at the dissection area reduces pain and inflammation, providing

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therapy at a plurality of locations enables treatment of more than one target site, disposing the drug on the lead or impregnating the drug on a membrane on the lead enables the lead to treat more areas more readily, anesthetic provides temporary relief from pain, antibiotics treat abnormal health conditions, impelling a plurality of drugs can treat more than one condition. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the system and method taught by Kieval with a transducer that provides sonophoresis; providing therapeutic treatment localized to a dissection path; that the pharmacological agent is provided at a plurality of locations on the lead body; that the pharmacological agent is impregnated into a membrane provided on the lead; that the pharmacological agent is disposed on a coating on the lead; that the pharmacological agent is an analgesic or anesthetic; that the pharmacological agent is an antibiotic; that impelling the pharmacological agent comprises generating ultrasonic waves for impelling the pharmacological agent ultrasonically, impelling a plurality of pharmacological agents, impelling a first pharmacological agent using electrophoresis and impelling a second pharmacological agent using sonophoresis; or delivering a can into subcutaneous non-intrathoracic tissue of the patient, the can comprising an electrode or electrically conductive region, and a pharmacological agent and impelling using phoresis the pharmacological agent from at least a portion of the can to the subcutaneous non-intrathoracic tissue because phonophoresis achieves greater penetration and more readily delivers an entire molecule, transducers transfer one form of energy to another form of energy, providing drug delivery at the dissection area reduces pain and

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inflammation, providing therapy at a plurality of locations enables treatment of more than one target site, disposing the drug on the lead or impregnating the drug on a membrane on the lead enables the lead to treat more areas more readily, anesthetic provides temporary relief from pain, antibiotics treat abnormal health conditions, impelling a plurality of drugs can treat more than one condition.

31. Additionally, claims 20, 23-24, and 27-28 are rejected as being unpatentable over Kieval in view of Shapland et al. Kieval in view of Shapland et al. disclose the system and method described above but does not expressly disclose the can providing the sonophoresis, that the pharmacological agent is impregnated into a membrane on the can, that the reservoir is coupled to a port on the can, or that the pharmacological agent covers at least 25% of the surface area of the can. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the system and method for providing cardiac therapy as taught by Kieval in view of Shapland et al, with the can providing the sonophoresis, that the pharmacological agent is impregnated into a membrane on the can, that the reservoir is coupled to a port on the can, or that the pharmacological agent covers at least 25% of the surface area of the can, respectively, because Applicant has not disclosed that can providing the sonophoresis, that the pharmacological agent is impregnated into a membrane on the can, that the reservoir is coupled to a port on the can, or that the pharmacological agent covers at least 25% of the surface area of the can, respectively, provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the lead providing

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sonophoresis, the pharmacological agent disposed on the lead, that the reservoir is coupled to the lead, that the agent covers a portion of the lead, respectively at taught by Kieval in view of Shapland et al, because it provides therapy to the target site, provides the drug to the area of discharge, and allows the lead to provide electrical stimulation, and since it appears to be an obvious matter of design choice to modify Kieval in view of Shapland et al. to obtain the invention as specified in the claims.

32. Additionally, claims 59-62 are rejected as being unpatentable over Kieval in view of Schroepfel et al (U.S. 5749909). Kieval teaches the system and method described above, but does not teach providing a power signal to the device, a DC voltage, an AC voltage, or a DC bias voltage with an AC signal alternating at an ultrasonic frequency. Schroepfel et al. disclose the DC power signal and an AC voltage and a DC bias voltage with an AC signal alternating at an ultrasonic frequency (see column 2, lines 35-50 and column 8, lines 47-64). Providing the power in such a way enables efficient recharging of the battery without invasively replacing the power source. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the system and method disclosed by Kieval with the power signals disclosed by Schroepfel et al. in order to non-invasively replace power in the device.

Response to Arguments

33. Applicant's arguments with respect to claims 1-66 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment. Please note that the Kieval reference is considered to anticipate claim 1, for instance, because

the system provides electrical stimulation that controls cardiac function (or cardiac electrical stimulation).

Conclusion

34. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Heil, Jr. et al. (US 6,304,786) is one of many teachings of providing a lead with a membrane coating carrying various drugs, Shapland et al. (US 5,807,306) is one of many teachings of providing a porous doped polymer in an implantable device, Shapland et al. (US 5,282,785) is one of many teachings of providing a sonophoresis drug delivery apparatus, and Munshi (US 6,295,474) is one of many teachings of providing a coating with a variety embedded drugs.

35. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

1/12/07


GEORGE R. EVANISKO
PRIMARY EXAMINER

1/14/07